



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/790,540	03/01/2004	Hanson S. Gifford III	HRT-0256C2	2779
27777	7590	12/29/2009	EXAMINER	
PHILIP S. JOHNSON			COMSTOCK, DAVID C	
JOHNSON & JOHNSON				
ONE JOHNSON & JOHNSON PLAZA			ART UNIT	PAPER NUMBER
NEW BRUNSWICK, NJ 08933-7003			3733	
			NOTIFICATION DATE	DELIVERY MODE
			12/29/2009	ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jnjuspatent@corus.jnj.com  
lhowd@its.jnj.com  
gsanche@its.jnj.com

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/790,540	GIFFORD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	DAVID COMSTOCK	3733	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 17 August 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 21-47 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) 21-38 is/are allowed.  
 6) Claim(s) 39-47 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 01 March 2004 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 39-47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The amendment made to claim 39 does not appear to make sense in the context of the existing claim language. The language "...the member is configured to bias the distal ends of the at least two staple members are substantially parallel..." as set forth in the amended claim, does not go together or make sense. For examination purposes, and as best understood, the claim is being interpreted as setting forth a member configured to at least in some way bias the ends of the staple member.

In addition, it is noted that the status identifier in claim 46 indicates that the claim has been amended but no markings or indication of an amendment are found.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 39-45 are rejected under 35 U.S.C. 102(e) as being anticipated by Tovey et al. ("Tovey", 5,478,354; cited by Applicant).

Tovey discloses the claimed invention including a device 50 comprising an annular ring 55 and at least two (three are illustrated) equally spaced staple members 52-54 and 56-58 extending therefrom (see, e.g., Figs. 3, 4 and 6 and col. 4, lines 1-21). The ring is disposed about a central axis. Each of the staple members has a distal end. A member, e.g., 69, is configured to be disposed within the ring. The member is movable along the central axis relative to the ring. The device has a first configuration where the member is disposed within the ring (e.g., while installing the ring) and a second configuration where the member is not disposed within the ring (e.g., after installation is complete). The distal ends of the at least two staple members are substantially parallel to the central axis in a first configuration (e.g., Fig. 3) and the distal ends of the at least two staple members are substantially orthogonal to the central axis in a second configuration (e.g., Fig. 6). The device can be formed of a superelastic material such as a shape-memory titanium alloy (see, e.g., col. 2, lines 4-6 and col. 4, lines 27-30). A driver, e.g., 67, is disposed about (i.e. along or near) the member and is movable with respect to the member. The driver is configured to move the ring from a first position relative to the member to a second position relative to the member, whereat the at least two staple members engage tissue.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tovey et al. ("Tovey", 5,478,354; cited by Applicant).

Tovey discloses the claimed invention except for explicitly reciting that the staple members could extend from an inner periphery of the ring member. However, it would have been obvious to a person having ordinary skill in the art to have configured the device and formed the staple members to extend from an inner periphery of a ring member, e.g., to provide an alternate clamping arrangement, since it has been held that mere relocation of parts of an invention involves only routine skill in the art. *In re Japikse*, 86 USPQ 70. It also would have been obvious to have provided at least four such staple members, e.g., to provide additional clamping force, since it has been held that mere duplication of the essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

***Allowable Subject Matter***

Claims 21-38 are allowable over the prior art of record. While some of independent claim 21 is anticipated by Tovey, the relevant embodiment (e.g., Fig. 3, etc.) of Tovey lacks a member configured to bias (or at least capable of biasing) the

distal portions of the at least two staple members to the first configuration when the member is disposed within the ring. While another embodiment (i.e., Figs. 10 and 11) utilizes a configuration wherein a member is configured to bias the staple members to a first configuration, parallel to a central axis, it appears that Tovey et al. require a staple having an undulating shape in connection therewith. The undulating staple does not have a distal portion that is parallel (or orthogonal) to the central axis in any configuration. No other known art discloses or suggests all of the limitations of independent claim 21.

### ***Response to Arguments***

Applicant's arguments filed 17 August 2009, regarding amended claim 39, have been fully considered but they are not persuasive.

It is noted that member 69 can be considered to be configured to bias the distal ends of the staple members, as set forth in claim 39, at least because it provides the necessary resistance and support to the staple member against which the driving means acts (see, e.g., col. 4, lines 17-21). Moreover, without the member 69, the ends could not be biased. The driving means is not biasing the distal ends of the staple alone, but rather requires the resistance of the member 69. Accordingly, the member is also considered to be configured to bias the distal ends of the staple members.

Applicant is invited to contact the Examiner for an interview if it is believed this would help to advance prosecution and arrive at language to place the application into condition for allowance.

***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Comstock whose telephone number is (571) 272-4710 (a detailed message should be left if Examiner is unavailable). If attempts to reach the Examiner by telephone or voicemail are unsuccessful, the examiner's supervisor, Eduardo Robert, can be reached at (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

Should you have questions on access to the Private PAIR system, contact the  
Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/David Comstock/

Examiner, Art Unit 3733

/Eduardo C. Robert/

Supervisory Patent Examiner, Art Unit 3733